

Disposable Paper Filter for Sterilization Containers/Stryker Leibinger GmbH/ Recall (10/15)

Reason/Information:

Stryker issued a Urgent Field Safety Notice on the following materiel. Reason: Stryker has become aware that the inhomogeneity of the filter paper might potentially compromise the ability of the filter to maintain a sterile barrier during post-sterilization shelf-life.

Disposition/Instructions:

Immediate Actions To Be Taken By The Customer:

1. Immediately check internal inventory and quarantine all subject devices pending to scrap all affected materials at customer's location or return to Stryker.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within customer's facility.
4. Inform Stryker if any of the subject devices have been distributed to other organizations.

---Provide contact details so that Stryker can inform the recipients appropriately.

---If customers are a Distributor, note that customers are responsible for notifying their affected customers.

5. Inform Stryker of any adverse events concerning the use of the subject devices. Comply with any local regulations concerning the notification of adverse events to the local National or local Competent Authorities.
6. Complete the customer response form (See Image on Message under Additional Documentation/Attachment). It may be that customers no longer have any physical inventory on site. Completing this form will allow Stryker to update their records and will also negate the need for Stryker to send any further unnecessary communications on this matter. Therefore complete the customer response form even if customers longer have any of the subject devices in customer's physical inventory.
7. Return the completed form to customers nominated Stryker Representative for this PFA. Upon receipt of the form, a Stryker Representative will contact customers to organize any applicable ongoing actions.

Stryker requests that the customer respond to this notice within 7 calendar days from the date of receipt. The target date for completion of this action is 29 October 2015 and customer's timely response will enable us to ensure that Stryker meets this target.

If customers have any questions regarding this notification call Stryker Customer Service at 877-534-2464.

For more information on items affected, click [here](#).